Draft PRG Methods and Process Agreements

The LWG and EPA met on June 4, June 18, and July 2 to discuss PRGs. This document summarizes "agreements in principal" reached during those meetings regarding methods and process for developing "early" PRGs (i.e., PRGs developed prior to completion of the Baseline Risk Assessment [BLRA]). To accurately present the agreements in principle, this document contains excerpts from previous meeting minutes. No additional new information or interpretation is provided. As agreed during the July 2 meeting, EPA will review these agreements and respond to LWG within approximately two weeks. The goal of this response is for EPA to provide conditional approval for the LWG to proceed with the early PRG calculations, with conditions focusing on those issues/items that LWG should particularly consider during detailed PRG calculations. Note that if EPA develops new opinions or approaches in their response that have not been previously agreed to, this is expected to have direct impact on the early PRG development schedule discussed during the meetings.

It should also be noted that LWG acceptance of the agreements below should not be misconstrued as LWG agreement that the stated approach is the most technically correct. In several cases, LWG is willing to agree with the stated approach as a compromise on some technical issues in order to move the early PRG process development forward.

Agreements in Principle:

1. Overall PRG Process –
    a. Some type of early PRG process (prior to waiting for the conclusion of the BLRA) is needed in order to start the FS early.
    b. Early PRGs will be used to identify areas of potential concern (AOPCs) and begin early development of the Alternatives Development and Screening Report.
    c. The early PRG process would be for most of the chemicals that are believed likely to pose a risk level of concern once the findings of the BLRA are completely known.
    d. The early PRG list is not meant as a final list. An essential later step in the FS development process will be refinement of the early PRG list based on the findings of the BLRA

2. Early PRG Schedule and Review Process –
    a. It was agreed that the negotiation and review process needs to be streamlined in order for early PRGs to actually be developed at the pace needed. Over the course of the meetings the following milestones were developed:
        i. Early July - Agreement on PRG methods
        ii. July 11 - LWG submit summary agreements (this document)
        iii. July 25 - EPA comment and approval with any additional items/issues for LWG to "watch out for"

iv. Approx. July - EPA agreement on diver exposure parameters and final sediment background methods
v. Approx. August - LWG to "check in" with EPA on list of PCB congeners to be used in PCB TEQ PRG (see below)
vi. October 2008 - Streamlined PRG submittal to EPA (see below).
vii. These milestones are dependent on receiving EPA comments on the BSAF methods and the Food Web Model

b. It was agreed that LWG would present a streamlined submittal (as defined in 2.c below) presenting PRG results and a streamlined EPA review of that submittal (rather than a detailed report and comprehensive review).

c. It was agreed that the streamlined PRG submittal would contain a table of all calculated PRGs, notes for reasons why any PRGs could not be developed, and notes for any PRGs that are based on broad assumptions or extrapolations. Also, brief companion text describing the basic approach to deriving the PRGs would be included.

3. FS/PRG Terms - The concept of flexible refinement of PRGs during the pre-FS and FS process appears acceptable. Although EPA has referred to "refined PRGs" as "RGs" in some comments, there is no critical need for an additional term.

4. PRG Chemical List
   a. It was agreed that the chemical list for early PRG development would be inclusive of most of the chemicals expected to pose a risk level of concern in the BLRA (as well as can be predicted at this time).
   b. It was agreed that this list would be developed on a receptor basis for ecological risks and a pathway basis for human health risks. This would result in a matrix of chemicals on one axis vs. receptor/pathways on the other axis, with an "X" (or similar) in those boxes where PRGs would be developed (see draft list in attached Hand Outs 1 and 2).

5. Specific PRG Methods Agreements
   a. It was agreed that the streamlined PRG submittal would contain PRGs in "increments" for each receptor/pathway including:
      i. Human Health - It was agreed that representative PRGs will be developed for each target risk level (i.e., 10^{-4}, 10^{-5}, 10^{-6}, and HQ of 1) for the lowest and highest intake assumptions and, in the case of fish ingestion, for a single species diet those species consumed by humans with the lowest and highest BSAFs or FWM relationship. The idea of developing a "PRG curve" that would allow quick calculation of any theoretically possible PRG was also discussed, and EPA was amenable to this idea.
      ii. Ecological - One target level for each ecological receptor
   b. For **bioaccumulation-based PRGs** the following general approach was agreed to:

i. FWM or BSAFs (depending on chemical) would be used to calculate sediment concentrations that meet target tissue levels
ii. Water concentration in the FWM would be set to zero and background (as defined by background group), yielding two PRGs for each receptor/pathway increment.
iii. BSAF development will follow Burkhardt (2006) guidance (taking into account EPA's pending comments on BSAF development in Round 2 Report).

c. For **benthic toxicity** PRGs the following was agreed to:
   i. The logistic regression and floating percentile models will be used to define site specific thresholds
   ii. Narrative PRGs based on toxicity benchmarks (bioassay hit criteria) applied to bioassay results
   iii. Guidance Sediment Quality Values (SQVs) may also be used to define thresholds

   Whether and how these three lines of evidence can be weighted and combined to map areas of concern was discussed but **not** agreed to. It was agreed this could be part of later conversations on the BERA and area of concern development.

d. For **human health direct contact** sediment PRGs, it was agreed that these would be back calculated following RAGs guidance. It was noted that diver exposure parameters had not yet been defined, but EPA/LWG would do so within next two weeks.

e. For **ecological dietary-**based PRGs the following was agreed to:
   i. Follow methods consistent with the above bioaccumulation-based PRGs
   ii. Prey fractions will be set consistent with the BERA approach

f. PRGs Development for TEQ Chemicals
   i. It was agreed that LWG would conduct an evaluation to identify the congener or congeners most contributing to PCB and/or dioxin exposure in the river. The model would then be run for the specific congener(s) only and used to estimate any overall TEQ PRG based on those results.
   ii. It was also agreed that LWG would provide the results of the selection of the congener(s) to EPA before proceeding with the PRG calculation step.
   iii. It was also agreed that if the approach did not work (i.e., a sufficiently small subset of congeners could not be identified) then the LWG would propose an alternative method at that time. The alternative method is expected to be to use a weighted average Kow of all the congeners and run one representative congener in the model using this average Kow value.

6. Background – It was agreed that the background sediment values currently being developed using methods agreed to in EPA/LWG background meetings would be placed on the PRG tables to provide context to the PRGs.

a. It was recognized that there was one last step in the background development review process currently ongoing and that EPA needs to approve that final submittal before background values can be developed. LWG plans to submit this last piece of information, illustrating upstream sediment data reduction and outlier evaluation for several example chemicals, in a few days [Note: Background Outlier Evaluation Memo was submitted to EPA on July 3, 2008].